Position Paper

Recommendations for Health Canada on the integration of the edible cannabis and cannabis extracts into the Cannabis Act.

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INTRODUCTION

Bill C-45 (the Cannabis Act) has been in effect since October 17, 2018. The Task Force on Cannabis Legalization and Regulation established recommendations to protect public health and minimize harms, which has allowed for variations in Provincial & Territorial implementation policies for the recreational market. With phase one of cannabis legalization underway, the differing Provincial/Territorial models have begun to demonstrate the various impacts around adult-use non-medical, and patient-use medical cannabis product needs, supply concerns, and pricing.

Edible cannabis products make up a significant and growing portion of the existing illicit cannabis economy in Canada and in legal US jurisdictions. It is expected that edible cannabis products will continue to grow in both market share and overall popularity as Canada moves towards the regulation of these products.

While there are some current market operators who strive toward setting manufacturing standards and patient care, the overall lack of oversight and accountability for the edible cannabis products that are currently available for purchase puts the public at greater risk.

An identifiable legal market is imperative to capturing new consumers, while a comprehensive product selection within this new market will be crucial in persuading existing consumers to transition away from unregulated distribution and production channels. This new market will help in combating the risks to public health of the current unregulated market and secure the general social acceptance of public health and safety focus for edible cannabis and cannabis extracts.

Edible cannabis products are becoming commonplace and democratized. They are no longer a means to an end; consumers want to enjoy the consumption experience itself, not just the resulting effects. Edible cannabis has a wider appeal than smoking cannabis, since they are less conspicuous to consume and don't present the same harmful health effects as consumption by combustion. Gelatin-based confectionary products have long led the pack in sales, but chocolate, tincture, and pill sales have all risen dramatically in recent years.

In Colorado, 64 percent of adult-use cannabis customers tried an edible cannabis; the number is 55 percent in California. California, the Unites States' largest cannabis market, saw 108 percent growth in edible cannabis sales in 2018. Edible cannabis is projected to grow from 12 percent to 14 percent of the total cannabis market by 2022, while dried flower will drop from 50 percent to 36 percent. Edible cannabis' share of the total cannabis market has already more than doubled, from 5.4 percent in 2011 to the current 12 percent.

A Deloitte report from June 2018 found that 6 out of 10 consumers are expected to choose edible cannabis products. Several US states will have already sold hundreds of millions of

dollars' worth of chewable and drinkable cannabis. According to the cannabis data firm BDS Analytics, edible cannabis is the industry's fastest growing segment, alongside extracts.

According to Arcview Market Research via Forbes, consumers in California purchased $180 million worth of cannabis-infused food and drinks last year, which amounted to 10% of the state's total cannabis sales. Per a BDS Analytics and Green Market report, that percentage rose to 18% in February 2018, and there are no signs of it slowing. Another data firm, the Brightfield Group, projects that by 2020, America's edibles may net $5.3 billion USD. Worldwide sales of cannabis-based products are expected to reach $32 billion by 2022, up from $9.5 billion in 2017.[1]

The integration of edible cannabis and cannabis extracts into The Cannabis Act will be an important addition and will see positive benefits for all Canadians, notably in areas of personal health and overall burden on the Canadian healthcare system. Preventative health care measures (e.g. encouraging the avoidance of smoking) are known to have a positive effect on healthcare costs, and the availability of edible cannabis products will positively impact consumer health by providing a non-smoking option for cannabis consumption.

When building a framework of regulation to support this new market, consideration for public health and safety must be paramount. As the Government of Canada begins developing a comprehensive regulatory framework relating to edible cannabis and cannabis extracts, there is a need for collective positions to come together and develop standards that work within Canada. However, the development of this framework must also take into clear consideration the economic impacts and opportunities, social impacts, and environmental impact that this new industry will have. As this report will show, a primary focus on immediate public health safety need not sacrifice the long-term societal objectives of a healthy society and economy.

In keeping with the focus on public safety, this overview provides a summary of strategic elements the Government of Canada should consider in the development and finalization of regulations for edible cannabis and cannabis extracts while acknowledging the objectives of social wellbeing and economic opportunity for Canadians. In addition to the information acquired from markets such as Colorado and California, this overview reflects the experience of Canadian consumers and entrepreneurs and identifies the need to ensure that the final framework considers solutions that help protect Canadian health and safety without unnecessarily sacrificing social and economic opportunity and wellbeing.

Prepared by Dynaleo Inc., this paper aims to provide logical recommendations to policy makers on how to incorporate this new category of products into the supply chain in association with the introduction of new regulations during 2019. It is assumed that the Government of Canada has already consulted with the Canadian Food Inspection Agency (CFIA) and the Food Directorate, along with other regulatory bodies that set current standards for the health and safety of non-edible cannabis and cannabis consumable products in Canada.

KEY ELEMENTS

To promote a healthy, safe, and sustainable edible cannabis and cannabis extracts industry at all levels of the sector, the Government of Canada's regulatory regime for edible cannabis/hemp and cannabis/hemp extracts should address the following topics:

- Public health & safety
- Product quality assurance and dosing measures
- Packaging & labelling, including greater social- and environmental-impact concerns
- Training and certification programs for all levels of industry operators
- Small and medium business sector collaboration

A DEFINTION OF EDIBLES

For the purpose of this paper, when discussing 'edibles', we are considering only products that would traditionally be referred to as 'food', containing non-cannabis food ingredients with added cannabinoid-rich inputs. As such, capsules, oils, alcohol tinctures, and sublingual applications will not be addressed here. Products that would be traditionally considered 'food' present very specific regulatory challenges, as the end products rarely meet an acceptable standard in the unregulated market. The use of multiple ingredients creates concerns around potency and analytical testing, putting these products firmly in the realm of food regulations.

POSITION

Canada's regulatory framework for edible cannabis and cannabis extracts should establish a Federal health, safety, and business sustainability framework for dosing, packaging, processing, and manufacturing that meets the same standards for the biological and patient approach regarding other cannabis products, including:

- Standards that reflect and exceed quality and safety standards required in the United States
- Alignment with current Food and Drugs Act, along with the Controlled Drug and Substance Act
- Entrepreneurial business programs
- Environmental commitments
- Establishment of a group of standards and compliance provisions allowing for large and small businesses to succeed in product development using legal cannabis and hemp
- Defining how edible and consumable dosing will be governed under both cannabis for medical and non-medical use
- Allowing for chewable products such as, gelatin-based edible cannabis as a delivery method for cannabis-infused products that do not promote to youth
- Enable access to natural and healthy ingredients for the production of edible cannabis products

PUBLIC HEALTH & SAFETY

PUBLIC HEALTH IMPACTS

Moving towards phase two of the Cannabis Act, it is imperative to regulate an identifiable legal market, with selection and formats of products that support the development of a safe and sustainable future for legal cannabis products in Canada.

New cannabis consumers want products that are safe and reliable. Consumers want products that are consistent, which will be achieved by allowing the right selection of regulated edible cannabis to be part of the legal Canadian marketplace. Public safety challenges, as with all industries and sectors, needs to be heavily prioritized for the health and safety of all Canadians. This will be achieved by addressing public safety, dosing, potency limits, packaging, labelling, and market sustainability surrounding processing, manufacturing, storage, distribution, and consumption policies.

The current unregulated production and accessibility model of edible cannabis in Canada results in confusion for consumers as they fail to delineate between legal and illicit products. Patients and consumers need to be able to clearly identify products that have been produced under government-regulation product versus unregulated product based on packaging, availability, and authorized distribution channel access.

Access to well-regulated edible cannabis offers positive health opportunities that can be realized as a natural byproduct of their regulation. Reducing social stigma has shown time and again the mental health and societal benefits to those in society who have previously felt shamed or stigmatized. Regulation of edibles will inevitably reduce the stigma surrounding overall cannabis use. Edible cannabis specifically is also discrete and odourless, allowing both recreational and medical users to consume without being subjected to the stigmatic views traditionally associated with smoking. Edible cannabis may also offer a lessening of potential public nuisance with the absence of smoke or odour.

According to a study published by Dalhousie University, 93 percent of those in favor of cannabis legalization are very likely to try at least one edible cannabis product, while 59 percent worry about the risk legalized recreational use of cannabis will have on young children and teenagers.[2] In Canada, indications can be taken from the volume of cannabis patients and current retail sales that, demonstrates an acceptance for cannabis legalization, and a reduction of stigma in general.

PRODUCT QUALITY ASSURANCE AND PRODUCTION

Regulations should be established to control minimum standards for quality assurance and production used throughout the edible cannabis and cannabis extracts manufacturing process,

particularly regarding cannabinoid level control and tracking, testing standards, and product type.

While this may seem obvious, extraction providers should be required to complete detailed qualitative and quantitative reports about their finished products that may be accessed by regulators and B2B partners. These reports should be required to demonstrate that the final extraction products meet or exceed all related Health Canada standards.

Further to extraction and ingredient standards, the manufacturing facility developing and producing edible cannabis and cannabis extracts must meet a set of minimum standards related to processing and handling, storage, security, and emissions.

Since the production of edible products requires handling identical to commercial food products, it is our recommendation that the production of edibles should be regulated as part of the Food and Drugs Act. We recommend that facilities producing edible cannabis follow (Section C.02.001 - DIVISION 2 - Good Manufacturing Practices and section B.01.401 - Nutrition Labelling) of the Food and Drugs Act. By regulating edible cannabis as a food product, facilities will be required to adhere to the CFIA's General Principles of Food Hygiene, Composition and Labelling to protect themselves, their employees, and consumers. Regulating edible cannabis as part of the Food and Drugs Act also ensures that the final product will match the standards expected for an item intended for oral consumption.

Additionally, standardized analysis testing is critical to ensure that all products and ingredients are being tested and reported under the same conditions. Certified testing for ingredient oils is important from a manufacturing perspective so that unnecessary burdens are not placed onto smaller processors to ensure that the products they receive are consistent with their stated reports. From a product-testing standpoint, both the manufacturers and the at-home consumers will need to be able to rely on cannabinoid-level reports being consistent across Canada so that they can come to rely on these levels for successive use (industry) and familiarity (consumer). As cannabis edibles inevitably diversify in their formats, it is critical that the same product-testing procedures and standards are being applied. The government should work with current licensed testing & analysis companies to produce a set of standards under which edible cannabis products will be tested to ensure this is constant across Canada.

The advantage of allowing for the manufacturing of products with high degrees of homogeneity and dosage control, such as gelatin-based products, chocolates, and other internally homogenous products is that it provides the opportunity for more precise and accurate dosing. Products that are highly homogenous are easier to dose consistently when a single product is designed to broken up into multiple doses, such as a chocolate bar. Homogenous products are also easier to dose with greater precision, which has the added benefit of helping small- and medium-sized businesses with overcoming the challenges of precision dosing simply by including these product formats within the regulatory framework. Chewable products already exist in the OTC, nutraceutical, natural health, and vitamin markets with great precision and

therefore should be allowed as part of edible cannabis format to remain consistent with current Canadian policy on acceptable drug formats.

It is important to offer these formats in the legal market to help dissuade consumers from continuing to seek out unregulated products that are not accurately dosed, labelled, or meet strict food safety standards. Prevention and harm reduction strategies ensuring public safety must allow for these product formats so that they can be controlled and regulated through packaging and distribution, as consumers have already shown a strong preference for these products and may continue to seek them out through unregulated means. Childproof packaging and product-labelling requirements will ensure that these products can be manufactured in a manner that is safe for public consumption.

Edible cannabis should also follow the Cannabis Act to ensure that the production facility maintains the same security standards expected from cannabis licensees, specifically regarding access to the production area and the storage of ingredients containing cannabis. However, relative to dried flower, finished edible cannabis products will more likely have a low value relative to their weight and can take considerable space to store relative to their value, especially considering requirements for refrigeration. The policy for storage of the finished product should be no more restrictive than policies for other controlled substances, such as alcohol and tobacco. We recommend that storage areas containing finished edible cannabis be restricted via key or code entry access to designated employees such as a supervisor or onsite manager, and video surveillance should be used to monitor the area. Based on the value and the low doses found in the finished product, no other security measures should be required for storage. This is in line with our further recommendations on reducing the economic burden on small- and medium-sized businesses.

DOSING AND FORMATS

Allowing for products to contain multiple doses per contiguous unit should be explored and given a range of acceptable implementation practices across standard and microprocessors, as well as format types. Homogeneity of the dosed portions of the product is critical when multiple individual doses are attached in a single unit.

A contiguous unit is defined as a single unit where the contents are highly homogenous and the active pharmaceutical ingredients (API's) a contained in the same proportions relative to any single portion of the unit achieve by division.

When divided, a contiguous unit contains an amount of API equal to the total weight of a single divided portion multiplied by the ratio of total API to the total weight of the unit. Simple examples of this include a bottle of liquid containing an un-separated solution (does not require shaking), or a chocolate bar containing no added solid ingredients beyond those used in the chocolate-making process.

In homogenous and contiguous products, dosing can be easily identified and controlled by using clearly identified shapes and demarcated portions. Often this will require the use of specialized molds and forms.

Allowing for products to contain multiple doses per unit will offset financial difficulties that would otherwise create potential barriers for small and medium-sized company's entering the edible cannabis market, who may otherwise be forced to produce single stand-alone servings containing a maximum of 10mg of THC (as defined by current regulations).

From a health, safety, and business perspective, a high degree of homogeneity simplifies dosing through portion control, size, and weight restraints. This is key to developing effective guidelines and practices upon the legalization of edible cannabis.

Dosing information is an important source of consumer self-regulation and it is vital that the total names, formats, and total dosage per serving (or per dose) be as accurate as possible. Where possible, this includes the effects of the different compounds, and mixtures with all other cannabinoids and forms of those cannabinoids. The amount of each cannabinoid in each of its forms that are present (e.g. THC + THCA), should be shown on the label. It is important that all cannabinoids are tested for in the final product and shown on the label.

With regulated processing and manufacturing methods there would be no guesswork or approximations. Each individual piece can be accurately dosed and clearly marked so that consumers may confidently take the appropriate dose per desired effect. Additionally, and even more importantly for consumer's safety, consumers are able to much more quickly and safely learn exactly what dose is required to achieve that desired effect when there is standardization across product types.

Note that all cannabinoids have differing chemical structures and, as research into each cannabinoid begins to progress we will better understand the effects and efficacy of each. Note specifically that when ingested orally versus inhaled many cannabinoids, such as THC, are metabolized by the body differently and thus provide significantly different effects. As an opportunity to support safe consumption, the government may want to explore using conversion charts to educate consumers on the differences of each cannabinoid or requiring such charts to be published through medical and adult-use sales channels.

POTENCY LIMITS

Product titration is an important factor for consumers when choosing to consume THC-infused edible cannabis products. The 'start low and go-slow method' is strongly recommended by experienced consumers as a way to judge one's own tolerance for THC products. As THC is known to uniquely affect each individual, this method is the best way to introduce new

consumers to cannabis. However, this method is only appropriate and applicable when dosages and delivery methods are standardized and remain constant, as is the case with edible cannabis that exhibit a high degree of homogeneity and consistency.

Homemade edible cannabis is a perfect example of the failure of inconsistency. It is common to hear individual reports of homemade THC-infused products delivering inconsistent doses resulting in undesirable effects, which make it imperative from a public safety standpoint to introduce consistent and accurately dosed products with identified dose levels for consumers to quickly determine their preferred and tolerated dose.

Potency limits present a unique area of consideration as we continue to learn that cannabis reacts differently with each user. In the medical market, a standard maximum dose would be 20mg THC three times daily. Some studies have claimed that CBD can be used up to 1200mg per dose, but in practice most people will use up to 50mg of CBD twice daily. (Dr. Daniel Schecter, Toronto Physician). With this in mind, it would be relevant to consider higher allowable single-portion doses of CBD than THC.

While not heavily studied, many consider 10mg of THC a low enough dose to avoid the discomfort of accidental overconsumption. Additionally, a 10mg dose will wear off relatively quickly. For liquid ingestible cannabis extract, dosing instruments should be part of the package or common to all households (i.e. standard teaspoon).

According to a 2013 report from the Amendment 64 Task Force, the limit of 10mg THC was determined by compiling several scientific studies, anecdotal reports, and consultations from medical doctors.[3]

At 10mg, the average adult will fully feel the positive effects of THC with minimal adverse effects. The upper limit for this range is 20mg, but that can be too much for some people, and not enough for others.[4] This is yet another reason to create unit packages of 100mg THC instead of individually packaging pre-determined doses.

THC AND CBD LIMITS

With public health and safety at the forefront, it is recommended that each unit have a maximum THC content of 100mg, and each clearly-demarcated individual “serving” or “dose” have a maximum THC content of 10mg. CBD should not be limited until such a time as any negative effects from overconsumption of CBD have been identified, as it is non-intoxicating and is often used in significantly higher doses for medical and therapeutic purposes.

Based on this recommendation, a single unit would:

- Contain a maximum of 10 “standard” doses of 10mg, up to a total of 100mg per unit;
- Have each “dose” within the unit clearly demarcated and be easily identifiable by consumers for the purpose of portion control;

- "Doses" less than 10mg should be clearly identified as such.

PRODUCT ACTIVATION TIME

Similar to the supplement and OTC markets, there are different product release effects for cannabis based on product intention and format. In addition to consumer safety navigating product dosing, understanding product activation time will be important to ensure consumers understand the usage and experience parameters surrounding cannabis products. From immediate- to slow- and extended-release, these different product attributes should be defined for edible and consumable development so they may also be clearly labelled and presented to the consumer.

Inhalation of combusted dried flower or vaporized cannabinoids remains the most immediate and effective dose for users based on the current legal options including oil, capsules and sprays. Controlled dosing of most cannabis formats will see effects that can begin anywhere from immediately after consumption to up to 2.5 hours later, according to the user's mood and metabolism.

Especially for ingested cannabis, effects can be dependent on personal constitution, time of day, content of food consumption prior to ingestion, and overall health. Edible cannabis and cannabis extracts should be required to display on the label an estimated activation time under a standard and format that is similar to pharmaceutical grade products, whether intended for the medical or non-medical cannabis market.

INGREDIENTS

With regards to ingredients, the CFIA has already established a set of regulations that apply to food products that should further apply to edible cannabis and cannabis extracts designed for oral ingestion. Of notable concern are substances that are deemed unhealthy such as, high caffeine and fat levels, additives, dyes, and artificial ingredients.

With regards to caffeine limits, the Government of Canada has clearly indicated that caffeine is regulated as an additive under the Food and Drugs Regulations when infused in food and must be assessed by Health Canada prior to permission of any new use. As caffeine is a natural diuretic and stimulant, caution must be used when combining with any other known drug including, THC and CBD. That said Health Canada has "re-confirmed, that for the average adult, moderate daily caffeine intake at dose levels of 400mg/day is not associated with any adverse effects." However, consumption of THC and CBD in conjunction with caffeine should be avoided, as the short- or long-term adverse health risks associated with combining cannabis and caffeine are not yet known.[5]

While it is unlikely to be considered in specific regulations by Health Canada, the use of low-impact ingredients and processes should be permitted and encouraged wherever possible.

Health Canada has a unique opportunity to play a role in shaping the very long-term health of Canadians by looking at opportunities to promote the use of low health-impact ingredients and production processes wherever possible. This opportunity should be taken to see where regulation might support producers who wish to use locally-sourced or environmentally-friendly ingredients and processes, as well as ingredients and processes that are generally accepted as positive for public health. In consideration for dietary restrictions and overall consumer health, low-sugar products should be supported, along with limited use, if any use, of synthetic sweeteners in edible cannabis products.

It is our recommendation that the cannabis oils used for edible cannabis should initially be allowed to be extracted with no maximum potency. Using traditional oils as a carrier for cannabis oil also provides access to food production methods that increase homogeneity in the final product. As stated previously, increasing homogeneity of the ingredients carrying the API directly translates into a potential increase in product and dosage consistency. Highly concentrated oils will always be diluted during production with other ingredients and will neither be the final product nor available for retail sale.

Using higher initial concentrations of cannabis oils will allow for more consistent dilution, and invariably dosing and products. If initial cannabis extract oils are required to be diluted prior to ownership by an edibles-production company, it would render many edible cannabis products impossible to produce, including many product formats that can be the most consistent and homogenous. Chocolates and gelatin-based products are perfect examples of products that are exceptionally easy to accurately dose but are disproportionately affected by even small amounts of dilution by the addition of other oils. Cannabis oil ingredients that are produced through extraction processes for the purpose of use in edibles should have no maximum potency and should not require dilution prior to being received by a manufacturer of edible cannabis products.

In anticipation of production regulation overlap, we recommend that cannabis oils be produced to a food-grade standard, ensuring that these products can then be used in the production food products within the current guidelines set out in the Food and Drugs Act for the addition of a fat (Section Marketing Authorization for Food Additives That May Be Used as Carrier or Extraction Solvents (SOR/2012-216) Marketing Authorization for Food Additives That May Be Used as Emulsifying, Gelling, Stabilizing or Thickening Agents (SOR/2012-205)[7]. We define food-grade as meeting the same testing parameters as other oils already found on the shelves of grocery stores.

INCORPORATING QUALITY ASSURANCE

By regulating edible cannabis under the Food and Drugs Act, quality assurance is a much simpler process. Edible cannabis should be expected to provide both quality and dosing accuracy. Finished edible cannabis can be tested for food safety and quality according to current guidelines set out by the CFIA, including the presence of standard bacteria, mold, and

chemicals currently tested for in other food products. Using the food safety testing guidelines in the Food and Drugs Regulations, manufacturers will have access to an established framework that will be crucial to ensuring quality from the start.

Testing is paramount, but government-mandated testing for edible cannabis should only be required for the finished product, as opposed to any required testing for work in progress (or unfinished goods). Cannabis oils used as ingredients should be tested and reported as mentioned previously.

The finished product must be tested for potency and all harmful materials, and the frequency of these tests should be further discussed to create a reasonable way of working. Testing every single batch is unnecessary, unreasonable, and will put an enormous financial burden onto the producer. This financial burden will ultimately disproportionately affect small businesses due to their expected smaller batch volumes. Additionally, while current testing standards for smoked or inhaled cannabis products are stringent by necessity, all harmful materials tests should be no more stringent than requirements for all other food products under the Food & Drugs Act.

The government should consider testing programs that require every producer to prove their capability in consistently producing a safe and accurate product. For new products being introduced to the market, the following is recommended regarding potency and harmful materials:

- Each unique product should require three unique batches to be produced, and each batch to have at least two units selected at random from the batch and tested. No single unit should be outside of +/-10 percent of the labelled dose. No single batch should be outside of the range of accepted levels of any materials or chemicals considered harmful under the Food and Drugs Act.
- On an on-going basis, products that have already passed this “market readiness” test and have been on the market should undergo “lot testing” to ensure ongoing accuracy and consistency. Each product should be labelled with the “expected potency” (e.g. 10mg per cookie) and also labelled with the average potency of the “lot” (e.g. 10.32mg THC)

These recommendations come directly from producers whose primary objectives were to consistently produce an accurately-dosed product and ensure that consistency did not decline over time. This is in accordance with experience in both small-business and small-batch production.

All ingredients used in the production of edible cannabis should follow tracking protocols already covered by the CFIA, in the event of a recall. Using the reporting outlined in (Section: 81 - PART 6 - Cannabis Tracking System)[7] of The Cannabis Act, the extracted oils can be handled and tracked like other cannabis products. Doing so will ensure consumer

safety and product security. Products should also adhere to the reporting guidelines found in The Food and Drugs Act to ensure consumer safety in the event of a recall.

PROCESSING AND BEST PRACTICE METHODS

The production of edible cannabis is not un-like the production of any other food and beverage product, with the exception of adding THC and/or CBD as an API. Adherence to the CFIA's Safe Food Production should be a non-negotiable. Guidelines and recommendations are of benefit to producing a homogenous and consistent end-product and could be created as an aid to industry. The objective is to produce safe and regulated products for the end user to consume with confidence.

Furthermore, environmental efficiencies should apply with regards to eliminating; recollecting and, re-capturing waste when producing edible cannabis and cannabis extracts, as already used in mainstream food and beverage manufacturing.

Another consideration is the importance of minimizing opportunities for error during production. For the purpose of reducing this, we recommend that manufacturers be required to use Hazard analysis and critical control points (HACCP) and prepare documented SOPs to ensure consistent production. Operations and manufacturing steps should also be outlined in a way that minimizes the number of steps required while focusing on accuracy to prevent the possibility of errors.

EXTRACTION METHODS

To ensure product and consumer safety, restricted chemicals and solvents will remain under government control. The Government of Canada recently released a list that included an update of usable solvents for cannabis oil products in Canada. The list offers licensed producers a wider variety of extraction options including C02, Ethanol, and Hydrocarbons[6].

Regulations for cannabis extracts and other formats will continue to impact the development of the legal cannabis market. Extraction, which allows for cannabinoid fractioning and in turn provides an oil or powder-based output, highlights the point that cannabis will be extracted into many forms and formulas. This is a key area that should be considered to ensure that all permitted extract forms are safe to use for the development of edible cannabis and cannabis extracts.

As there will be many formulations of cannabis extracts to be developed in the coming years, it will be critical to set up testing labs and services to best understand how various extracts, and subsequently edible cannabis and cannabis extracts can be a safe, healthy and effective way to attain desired consumer effects.

Many food grade extraction methods, which include hydrocarbons and alcohol, are still regulated for use under the legal Canadian cannabis market. Current food safety measures provide a standard set of methods, which can be accessed by large, medium and small-sized businesses. The same methods used across food and beverage in Canada should be used to help stabilize and develop the cannabis market.

SHELF LIFE STANDARDS - BEST BEFORE DATES / EXPIRY

In the current legal cannabis market, expiry and best before dates are not standardized. In particular, carrier oils are not governed under the cannabis act and can get rancid if not stored properly. Current licensed producers are using food standards for carrier oils as a shelf life guideline. Current licensed warehouses, along with provincial recreational warehousing have not fully adapted to controlled refrigerated storage centers for products that require additional handling. It will be critical for the government of Canada to set best-before and expiry dates around ingredients and formats to ensure that product can be controlled, returned, and stored properly to guarantee that cannabis, as an ingredient, does not create any unnecessary harm.

Little is still known about the rate at which cannabinoids break down once they have been added to unique food products. As such, consideration should be given to additional regulations that allow for the potential of this inconsistency over time. In addition to being used as a food safety guideline, best before dates should reflect, as best as possible, an accurate representation of the expected potency within a specified margin of error, e.g. +/-10 percent if stored according to directed instructions.

While degradation of cannabinoids in a product is unlikely to substantially harm a consumer at the instance of consumption, it has the potential pose a danger in the future as the consumer comes to expect effects that are otherwise lower or weaker than “standard”, potentially leading to over-consumption in the future as a result. While the industry has limited experience with cannabinoid degradation in food, it is recommended to create a set of expected degradation standards for each food product type. Should this emerge as a known and expected issue, an approximate set of standards should be created as early as possible and kept updated as more information is gleaned industry-wide.

ATTRACTION OF PRODUCT

Ensuring cannabis products do not appeal to youth is a primary mandate for the Government of Canada, which will require strategies that will support this mission, facilitate the development of the legal edible cannabis and cannabis extracts market, and help combat unregulated production and distribution.

Edible cannabis should not be manufactured in a way that appeals to youth. This includes shapes and labels, as well as use terms like “candy” to describe the product. Current regulations require opaque and childproof packaging which should help eliminate almost all

instances of appeal to youth, provided that adult consumers take the same care with handling and storing the edible product contained within as they are expected to other OTC drugs.

To minimize further the potential for youth consumption shapes such as animals and recognizable or familiar characters should not be permitted. However, shapes that are not traditionally marketed, or designed to be marketed towards youth should be permitted for cannabis edible and consumable development.

Flavours or colours should not be banned from edible production, as they are often a natural result of the production processes, depending on the ingredients used. Restricting these would unreasonably restrict the types of ingredients that could be used in products (specifically fruits and spices).

PACKAGING AND LABELLING

PACKAGING SUSTAINABILITY

Wasteful packaging has already been a point of contention in the newly regulated cannabis market. The concern with current suggested edible cannabis regulations is that the packaging requirements will be even more wasteful and costly, therefore negatively impacting both the environment and small business initiatives.

Packaging for the legal cannabis industry has heavy requirements around childproof and tamper-proof mechanisms. The current volume of material used to include childproof requirements has left many Canadians wondering what the repercussion of packaging will mean for the environment.

Overall packaging sizes should be reconsidered to work towards a model that is in line with the future needs of environmental sustainability. Use of environmentally conscious products and materials should be a priority for the cannabis sector in keeping with other health and safety best practices. To this end, wrapping each individual dose adds unnecessary waste, is not environmentally conscious, and does mitigate consumption practices.

Furthermore, while servings should be easily discernible, we do not recommend that individual servings be separately packaged. Individual dose packaging, and the infrastructure required for such is extremely costly, especially for small businesses. Requiring this type of packaging would significantly hamper the ability of new businesses to emerge and improve their carbon footprint and overall sustainability. Allowing multiple “doses” to be provided within a single contiguous unit, as stated previously, can mitigate some of this downside.

Another consideration against individually-wrapped servings is that they do little to promote child safety. Under our suggested model, the child-resistant requirement of the entire package already falls to the outer packaging, and child resistant packaging should not be required for each individual piece or dose. Though child-proof barriers should be used where possible, it

makes little sense to include multiple child-proof barriers if a single one isn't already sufficient. To this end, multiple doses and products sold should be permitted within a single childproof packaging option.

The lack of affordability surrounding childproof packaging (and especially environmentally-friendly materials) will be a further barrier for both small- and medium-scale businesses and therefore, should become part of a larger plan involving the Federal Government. Packaging costs will mostly affect craft and small businesses, particularly those that do not have the preliminary capital for automated packaging lines or do not have the production space for such lines.

It is our recommendation that edible cannabis be packaged per unit, and not per dose. Per dose packaging is hugely wasteful and redundant. The unit packaging will already be compliant with Health Canada's regulations regarding childproofing and plain labelling. Packaged edible cannabis should not exceed 10mg of THC per dose and 100mg of THC per package. Edible cannabis should be produced in a way that allows each serving or dose to be easily identified and separated in the case of multiple servings per unit. Each serving should also be easy to distinguish to avoid accidental overconsumption.

LABELLING

Cannabis-infused products look like normal food, which means that education is required for safe adult use and protection of children and animals. To mitigate the risk of accidental overconsumption, labels need to be clear and have identifiable symbols to ensure manufacturers are appropriately packaging and labelling their different suites of products. We recommend adopting the internationally recognized standard diamond THC warning emblem for any products containing THC.

It is important to recognize that potential adult-use consumers and patients may have existing allergies, and therefore it is critical to ensure edible cannabis and cannabis extracts are labeled with clear markings of any possible allergens, such as dairy, nuts, gluten, and animal by-products, as would already be required by the Food and Drugs Act

As previously mentioned, the entire tested cannabinoid content should be shown on the label for all cannabinoids above a specified level (suggested 0.10mg). As an example, in a 10mg THC dosed-edible cannabis, other terpenes and cannabinoids are often relatively infinitesimal. While the amounts may be trace, a complete cannabinoid profile should be listed for all cannabinoids above a minimum potency level. A warning may be added, similar to an allergy-warning symbol or statement indicating, "cannabis contains trace terpenes and cannabinoids beyond what may be labelled that may cause allergies."

We may also see edible cannabis marketed for their flavonoid content. Flavonoids are another class of chemicals in cannabis that may influence the different kinds of highs consumers experience and should be indicated on the label where applicable.

Since edible cannabis has delayed effects, labels should also notify consumers of the variation of onset, which is related to many factors such as metabolic rate, body mass, and how much food has recently consumed.

Overall, labelling requirements should primarily ensure that labelling specific to edible cannabis are focused on educating and protecting the consumer, specifically what each unit contains in terms of total dose, dose division, and warnings about the variation in time-to-onset for individual products.

TRAINING AND CERTIFICATION OPTIONS FOR ALL LEVELS OF INDUSTRY OPERATORS

It is advisable that the Government of Canada should develop a published set of guidelines with an established comprehensive training program in collaboration with a standards association that ensures manufacturers and distributors follow regulations to produce safe consumption of edible cannabis and cannabis extracts. This will ensure best practices relating to edible cannabis and cannabis extracts. Furthermore, these programs should be affordable for all industry players and operators. The goal is to allow for rapid, advanced, responsible, and safe practices to emerge across all levels of business, and to support public and private manufacturer and retail channels.

Among other things, this training program should include a guideline for standard operating procedures and requirements, product development and shelf life expiry date and unique serial number requirements, and requirements for manufacturers to maintain a registry of all ingredients, extraction, and lab testing reports. Additionally, all staff must be certified in food safety.

Education programs and access channels should be available to consumers as well as manufacturers to track registered legal edible cannabis and cannabis extracts. Format regulation will come from offering a discreet, smoke-free option that can be used for patients and adult consumers in sensible and safe ways that can be easily identified from unregulated products.

SMALL- AND MEDIUM-SIZED BUSINESS SECTOR COLLABORATION

While not a regulatory measure, ongoing consultation with knowledgeable sector leaders in Canada, the United States, and around the world will help the Federal Government establish an international health and safety standard for cannabis extraction, processing, and manufacturing of edible cannabis and cannabis extracts and expedite the establishment of relevant regulations.

To realize this partnership opportunity, Health Canada should support the establishment of a national health and safety council for cannabis extraction, processing, and manufacturing of

edible cannabis that should adopt best practices from other sectors, establish a quality control model for the new sector, and help governments achieve shared public health and safety goals. The goal of the council, in addition to supporting Canada's evolution into a legal cannabis market, should be to support small and medium-sized businesses to ensure economic health for all levels across the sector.

Similar to the licensed producer cultivation model which provides different models and license combinations to be used as a way to drive business development, a business model for large to micro manufacturers should be established to ensure a healthy competitive landscape is developed for both the public and private business sectors.

BUSINESS DEVELOPMENT

Small to medium-sized business opportunities come at a more disproportionate cost to doing business than large-scale models. There are many areas that need to be considered to help small and medium-sized businesses gain a position in the new cannabis market such as access to raw material sources, volume cost breaks, pricing standards, and corporate social responsibility.

Sharing market insights and public safety guidelines, along with education and buying groups for raw materials can also bolster practices for small and medium-sized businesses.

Current packaging requirements, including childproofing, are challenging for small and medium-sized businesses due to the volume of material required which increases operational costs and lowers profit margins. Key areas for policy implementation that can support a small and medium-sized business model at the national and local level include:

- Sales and distribution channels, with consideration for future on-line sales access;
- Micro manufacturer options and programs;
- Marketplace development;
- Local provincial percent of sales base to allow local business to grow. This approach can be used a business strategy and leveraged from Licensed Producer joint ventures;
- Locally supported supply deals;
- Regulated label rights

CONCLUSION

As Canada moves into phase two of the Federal legalization of adult-use cannabis, it is imperative that we examine the unregulated market in an effort to both learn from it and combat it. Consumers have already dictated a demand for edible cannabis and cannabis extracts, and the Government's best strategy to displace the illegal market will be to implement regulatory controls that maintain a public health and safety approach while also providing adequate access to these products.

We should look to a regulatory framework that could be immediately established similar to those already in place in Colorado or Washington State that could effectively mitigate the food safety and dosing risks that experienced federally regulated licensed producers can operate within.

RECOMMENDATIONS:

1. Delineate between edible products containing THC and CBD.

2. Remove the requirement of a separate manufacturing facility for companies working with CBD rather than THC, which constrains companies intending to make edibles using CBD as a welfare product.

3. Establish a Federal health, safety, and business sustainability working group for dosing, packaging, processing, and manufacturing that meets the same standards for the biological and patient approach regarding other cannabis products, with a mandate to adapt regulatory aspects to the reality of Canada's food processors.

4. Review of Dosage Limitations. Ensure the Working Group established as per recommendation #2, identifies optimal dosage levels - per single dose and per unit of edible product. As one of the goals of cannabis legalization is to discourage black market activity, we believe the current dosage limitations in the draft regulations will ensure the proliferation of unregulated edible products.

5. Allow for homogenized packaged products, not single dose; which is environmentally irresponsible and cost prohibitive for with otherwise little- to no-benefit to public safety;

6. Ensure labelling specific to edible cannabis is focused on educating and protecting the consumer. Accurate and informative labelling on packages should

allow the consumer to obtain clear, accurate, complete information and enable them to make an informed purchase decision;

a. cannabinoid contents for the entire unit,
b. recommended serving size,
c. cannabinoid content of each serving,
d. expected time-to-onset of effects.

7. Require all labels for cannabis edibles to declare the presence of any food allergens, as is mandatory for conventional food and beverage products.

8. Transportation, inventory and warehousing: That transportation, inventory management and storage standards be in accordance with those set by the Canadian Food Inspection Agency and that inspections be carried out by the CFIA inspectors.

9. a) Licenses & Permits: R&D permits and licenses for processing and micro-processing should granted in 3-6 months. The current timelines for receiving licenses and permits is an unreasonable barrier to entry.

   b) Cannabis Edibles Craft License: that a number of limited craft cannabis edibles production licenses be addressed and ruled by a special permit.

10. Certifications: That food processors of edible products containing cannabis have the food safety guidelines and certifications recognized by the industry;
    a. Hazard Analysis Critical Control Point (HACCP). This certification frames good manufacturing practices.
    b. Annual Global Food Safety Initiative (GFSI) Hearing. This certification may be requested and granted depending on the product, the customer and its destination.

Based on these recommendations, we believe the government will be able to establish and implement a strictly regulated framework that permits the legal sales of a diverse range of cannabis products.

We look forward to collaborating with the government on the development of the edible cannabis and cannabis extracts regulations based on our expert knowledge of the industry, consumer demands, and public health and safety requirements.

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